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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,596

02/19/2004

Chen W. Liaw

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03/27/2006

COZEN O'CONNOR, P.C.

1900 MARKET STREET

PHILADELPHIA, PA 19103-3508

EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/782,596	Applicant(s) LIAW ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/19/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/19/04; 5/7/04; 12/20/05; 2/22/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-26) in the reply filed on 02/22/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Applicants' preliminary amendment filed on 02/22/2006 has been entered in full. Claims 1-4, 9-20, and 27 have been canceled. Claims 5-8 and 21-26 are pending and under consideration.

Information Disclosure Statement

3. The Information Disclosure Statements submitted on 02/19/2004, 05/07/2004, and 12/20/2005 have been considered by the Examiner.

Drawings

4. The drawings, Fig. 2A, 2B, 3, and 5, filed on 02/19/2004 are objected because they are too dark to be seen. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended

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drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections—35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-4, 9-20, and 27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 1-4, 9-20, and 27 are drawn to a method for identifying modulators of a G protein-coupled receptor (GPCR) comprising the polypeptide of SEQ ID NO: 20 or a variant of thereof. The claimed invention is not supported by either a specific and substantial asserted utility or a well-

established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not require further research.

The specification discloses the hARE-2 polypeptide of SEQ ID NO: 20, a putative GPCR, which shares 53% sequence homology to GPR27 (Table A, page 8) and that the hARE-2 polypeptide is expressed in the left and right cerebellum and in the substantia nigra (Table 27, page 27). Nonetheless, the specification fails to disclose the ligand of the putative GPCR, fails to provide any sufficient information or evidence on the biological functions or activities of the hARE-2 polypeptide of SEQ ID NO: 20, and fails to disclose a patentable utility for the claimed invention.

First, the invention lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The assertion that the hARE-2 polypeptide of SEQ ID NO: 20 has 53% sequence homology to GPR27 does not endow the hARE-2 polypeptide and the claimed invention with a specific and substantial utility due to the great diversity in structures and functions of the GPCR family (Ji et al., *J. Biol. Chem.* 273:17299-17302, 1998). The functions of a GPCR have to be determined experimentally. Therefore, even if the sequence analysis can place a GPCR into the GPCR family, such an assignment does not render a specific biological function and thus a well-established utility to the GPCR, as is the case here. It is noted that neither the instant disclosure nor the prior art

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teaches the specific biological functions of GPR27, which the hARE-2 polypeptide is compared with.

The state of the art is such that the biological functions of proteins are unpredictable solely based upon sequence homology. The prior art teaches that sequence-based methods for function prediction are inadequate (*Trends in Biotech* 18: 34-39, 2000). There are putative seven transmembrane molecules, which do not appear to be coupled to a G protein (Ji et al., *J. Biol. Chem.* 273:17299-17302, 1998; in particular, the 3rd paragraph of left column of page 17299). No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

Secondly, the present invention does not have a specific and substantial utility, as exemplified below. The specification asserts, for example, that the human orphan GPCR can be used to screen candidate compounds as inverse agonists, agonists or partial agonists (see, e.g., page 15). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The disclosure fails to identify the ligand and the biological functions of the hARE-2 polypeptide. Clearly, further research would be required to determine the functions of the hARE-2 polypeptide. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

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In summary, the present invention fails to satisfy the utility requirement under 35 U.S.C. 101.

7. Claims 1-4, 9-20, and 27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5-8 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 7, 21, and 24 are indefinite for the following reasons:

(i). They recite, in part (a), contacting said one or more compounds with membrane of a host cell that expresses said receptor. It is unclear whether the claim requires contacting said one or more compounds merely with membrane of a host cell or the receptor present in the membrane because if a host cell, e.g., *E. coli*, is used, the majority of the expressed polypeptide would be present in inclusion bodies, not in the membrane.

(ii). They recite "...inhibit or stimulate functionality of said receptor". It is unclear what functionality of said receptor is intended to be determined.

(iii). The steps of the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a candidate modulator is determined and correlated to the preamble.

The Examiner notes that a method usually has a contacting step, a detecting step, a selecting step, and a correlation step linking the detection/selection step to the goal set forth in the preamble.

It is also noted that a modulator encompasses both an agonist and an antagonist. The methods of claims 5-8 do not appear to be able to achieve the goal set forth in the preamble: identifying an antagonist because the polypeptide of SEQ ID NO: 20 is an orphan GPCR and its ligand is unknown. Likewise, claims 21-26 appears to use a constitutively active GPCR. Thus, the methods of claims 21-26 do not appear to be able to achieve the goal set forth in the preamble: identifying an agonist.

Claims 6, 8, 22, 23, 25, and 26 are rejected as dependent claims.

Claim Objections—Minor Informalities

10. Claims 7 and 8 are objected to because SEQ ID NO is spelled as "SEQ.ID.NO." in each claim. Appropriate correction is required.

Conclusion

11. No claims are allowed.

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Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.
Primary Examiner
March 22, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER